Guidelines on how to make the notification for foodstuffs for particular nutritional use - Placing on the market of infant formula and foods for special medical purposes

1 Introduction

An authority's actions must be based on the powers granted to it by legislation and laws must be strictly adhered to in activities performed by an authority. By their legal nature, instructions issued by authorities are not binding on other authorities or actors. Issues concerning the application of legislation are ultimately settled in a court of law.

These instructions tell how to make the notification of infant formulae and dietary foodstuffs for special medical purposes. The instructions contain both direct quotes from legislation and interpretations of the application of the legislation. Legislation is clearly separated from the rest of the text. The interpretations given in these instructions are the views of the Finnish Food Authority about how the legislation should be applied.

2 Definitions

Infant formulae and dietary foods for special medical purposes are included under foodstuffs for particular nutritional use.

Infant formula is a food intended for infants during the first months of life and satisfying by itself the nutritional requirements of such infants until the introduction of appropriate complementary feeding.

Dietary food for special medical purposes means a food that is specially processed or formulated and intended for the dietary management of patients, including infants, under medical supervision.
It is intended for the exclusive or partial nutrition of patients,

- with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food or of certain nutrients contained therein or metabolites, or
- with other medically-determined nutrient requirements and

- whose dietary management cannot be achieved by modification of the normal diet alone.

Other foodstuffs for particular nutritional use include infant follow-on formulae, processed cereal-based foods and other baby foods, and total diet replacements for weight management.

3 Legislation

The framework legislation for foodstuffs for particular nutritional use is:

- Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control

Key legislation on infant formulae:

- Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding (= Delegated Regulation on Infant Formulae)
    - The Regulation will apply from 22 February 2020, except in respect of infant formula and follow-on formula manufactured from protein hydrolysates, to which it will apply from 22 February 2021.

- Decree 1216/2007 of the Ministry of Trade and Industry on infant formula and follow-on formula
    - The Decree will continue to apply until 21 February 2020, except in respect of infant formula and follow-on formula manufactured from protein hydrolysates, to which it will apply until 21 February 2021.
    - This Decree transposes into national legislation Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae.

Key legislation on dietary foods for special medical purposes:

- Commission Delegated Regulation (EU) 2016/128 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for foods for special medical purposes (= Delegated Regulation on Foods for Special Medical Purposes)
    - The Regulation applies from 22 February 2019, except in respect of foods for special medical purposes developed to satisfy the nutritional requirements of infants, to which it shall apply from 22 February 2020.

EU legislation can be found in the EUR-Lex database and national legislation in the Finlex database.

4 Notification requirement

Notification is currently required in respect of foodstuffs for particular nutritional use that are to be placed on the market on the following products:

- Infant formulae
    - Except infant formulae manufactured from protein hydrolysates, for which notification will be required from 22 February 2021
- Dietary foods for special medical purposes, also those that are developed to satisfy the nutritional requirements of infants

Notification requirement is upcoming for:

- Some follow-on formulae:
    - As of 22 February 2021, notification is required for follow-on formulae containing substances other than those listed in Annex II to the Delegated Regulation on Infant Formulae
- Total diet replacements for weight management
    - Notification will be required from 27 October 2022

4.1 Legal basis for notifications

Under Article 12 of the Delegated Regulation on Infant Formulae (EU) No 2016/127, when infant formula is placed on the market, the food business operator shall notify the competent authority of each Member State where the product concerned is being marketed of the information appearing on the label, by sending to it a model of the label

used for the product, and any other information the competent authority may reasonably request to establish compliance with this Regulation.

Under Article 9 of the Deregulated Regulation on Foods for Special Medical Purposes (EU) 2016/128, when food for special medical purposes is placed on the market, the food business operator shall notify the competent authority of each Member State where the product concerned is being marketed of the information appearing on the label, by sending to it a model of the label used for the product. The competent authority may reasonably request other information to be sent to be able to establish compliance with this Regulation. A Member State may also exempt a food business operator from this requirement under a national system which ensures effective official control of the product concerned.

Where several food business operators, for example several importers, are responsible for a food, each actor who places the food on the market shall submit a notification for the food concerned. A new notification must be submitted whenever there is a major change in the composition of the product or when there is a change in the manufacturer, company for which the food is manufactured, importer or other party who places the product on the market. Notification must be made also as regards a change in the commercial name of a food (brand name), even if the composition of the food remains unchanged.

4.2 Making a notification

Notification is made either through the Finnish Food Authority's electronic service or by post.

A fee is charged for the receipt of notification as provided by the Decree of the Ministry of Agriculture and Forestry on the Fees Charged for Services Produced by the Finnish Food Agency (986/2019). A higher fee is charged for a notification received by post because it takes longer to process than notification received through the electronic service.

4.2.1 Notification made through the Finnish Food Authority's electronic service

Notification of the placing on the market of infant formula or dietary food for special medical purposes is made through the Finnish Food Authority's electronic service. Electronic notification forms are available in Finnish, Swedish and English. Logging in to the electronic service takes place on the Finnish Food Authority's website and it requires a Katso ID which is given by the Finnish Tax Authority.

In the electronic service, "*Notification on dietary foods for special medical purposes*" is chosen and the form from the "*Type of notification*" picklist depending on whether notification concerns the placing on the market of infant formula or a food for special medical purposes.

The same notification can be used to indicate different packaging sizes for the same product, provided that the composition of the products is exactly the same. However, different flavours are different products and must be declared by separate notification.

Once the notification has been successfully sent, the food business operator will receive a reply message from the Finnish Food Authority to the email address given in the notification.

Detailed instructions on how to use the Finnish Food Authority's electronic service can be found behind the "*Instructions*" button on the top bar of the electronic service.

4.2.2 Notification made without using the electronic service

If the food business operator, for one reason or another, is unable to submit the notification through the electronic service, the notification can be made by filling in the notification form on the Finnish Food Authority's website.

Notifications made without the electronic service must be sent to the Finnish Food Authority's Registry

- by post to **Finnish Food Authority / Registry, PL 200, 00027 RUOKAVIRASTO** or
- by email to **kirjaamo@ruokavirasto.fi**.

Receipt of notification submitted by post takes place in the same way as through the electronic service. An acknowledgment of receipt will be sent by email to the address given by the food business operator. A higher fee is charged for a notification received on a notification form because it takes longer to process than notification received through the electronic service.

4.3 Processing notifications at the Finnish Food Authority

The Finnish Food Authority considers the notification requirement to have been met once the notification, including all the necessary information and attachments, has been received by the Authority. A mandatory attachment is a model of the label, which must be clear and legible, also in electronic format. The Finnish Food Authority may request the food business operator to supplement the notification at a later date if the information provided is incomplete or unclear.

The Finnish Food Authority does not evaluate the regulatory compliance of the composition or package labelling of the product on the basis of the notification. Furthermore, receipt of the notification does not imply that the Finnish Food Authority would have approved the product as being in compliance with food regulations.

The food business operator is responsible for ensuring that the food notified is in conformance with the legislation applicable to it. This also requires the food business operator to carry out an own-check as provided by foodstuff regulations. The operator must have a system in place to enable it to ensure that the product is in conformance with the relevant requirements of foodstuff legislation.

The information and attachments of the notification received are sent to the municipal food control authority and the Regional State Administration Agency for information and monitoring purposes. In addition, the Finnish Food Authority may, if necessary, send information to other supervisory authorities, e.g. the customs authorities.

5 Information about the food to be notified

In addition to the information required by the delegated regulations, the notification form also collects mandatory food information under the Food Information Regulation.

5.1 Commercial product name

Commercial product name means the brand name of the product.

5.2 Name of the food

The name of the food must be the name laid down in legislation of the European Community or, in the absence thereof, the name laid down for use in Finland. If there is no such name, the name of the food must be the established name generally used in Finland or a name that describes the food and, if necessary, its use so as to accurately identify the food in question and distinguish it from foods with which it could otherwise be confused.

The name of infant formula must comply with the names, which are infant formula or infant milk, as laid down in Article 5 of the Delegated Regulation on Infant Formula. The names may be supplemented with words describing the state of the formula (e.g. powdered) or its use (e.g. ready for use).

The name of dietary foods for special medical purposes is laid down in Article 4 and in Annex IV of the Delegated Regulation on Foods for Special Medical Purposes, which is: Dietary foods for special medical purposes. In Finland, the product may also be called a clinical nutrient supplement. The names may be supplemented with words describing the formula or its use.

5.3 Food group, category and item

The electronic form classifies foods into food groups and categories to make the food search easier. The grouping and classification of food has been adapted from the EFSA FoodEx2 classification system of the European Food Safety Authority.

First the group to which the product belongs is selected from the food group picklist. The food group for Foodstuffs for particular nutritional use is "Dietary foods for special medical purposes”.

The food categories are determined based on the food group selected in the electronic form. The appropriate food class, 'powdered infant formulae', 'dietary foods for special medical purposes' or 'liquid infant formulae', is selected from the picklist.

The foods in the **food** picklist on the electronic form are defined based on the food group selected. The food selection groups for dietary foods for special purposes are nutritionally complete or nutritionally incomplete. The food selection groups for infant formulae are selected according to the protein source of the formula, which are: cows' milk and goats' milk protein, protein hydrolysates or soya protein isolates.

5.4 Country of origin

Country of origin labelling means indicating, on the packaging or otherwise, the country or region of origin that the food comes from. In practice, country of origin means the country in which the food is manufactured.

5.5 List of ingredients

The list of ingredients tells which ingredients were used to make the food. The ingredients of a food are listed in descending order by weight at the time of manufacture. All the ingredients must be entered, a simple reference to the accompanying labelling is not enough.

5.6 Nutrition labelling

Information on nutritional composition is declared for each product ready for use.

Infant formulae

The energy content of infant formula is expressed per 100 kJ/100 ml or 100 kcal/100 ml. The amounts of fat, fatty acids and carbohydrates are expressed in terms of the amount of energy of the product either per 100 kJ or 100 kcal. The exception is lactose, which must be expressed as g/100 ml.

Each vitamin and mineral added to the product is declared in a separate section on the electronic form. Selection of "*+ Add vitamin/mineral"* will open a field with a picklist from which the vitamin/mineral selected is added. The chemical compound in the form of which the vitamin or mineral has been added to the food can be selected from the "*Chemical compound used*" picklist. If the food is supplemented with more than one vitamin or

mineral, re-select *"+ Add vitamin/mineral"* and complete the information. The sections must be carefully completed for all added vitamins and minerals. The amounts of vitamins and minerals are expressed in terms of the amount of energy of the product either per 100 kJ or 100 kcal.

The electronic form may also be used to declare the addition of a nutrient or substance other than a vitamin or a mineral to a food. Other substance is added by pressing the "+" button, and then selecting the substance from the picklist. A substance may be selected straight from the picklist or substances may be filtered by first selecting the substance category. If the substance is not on the list, the name of the substance can be entered in the empty field by selecting "*If the substance is not on the list, open here*". The amount of other substance is also given in terms of amount of energy either per 100 kJ or 100 kcal.

Dietary foods for special medical purposes

The vitamin and/or mineral to be declared in the electronic form is added in the same way as for infant formula. The amounts of vitamins and minerals are expressed, however, in terms of the amount of energy in the product either per 100 kJ or 100 kcal.

The vitamin and/or mineral to be declared in the electronic form is added in the same way as for infant formula. The amounts of vitamins and minerals are expressed, however, in terms of the amount of energy in the product i.e. per 100 kJ or 100 kcal.

Those substances which it is necessary to declare for the appropriate intended use of the product are declared under Other nutrients or substances. The amount of these substances is also expressed per 100 kJ or 100 kcal.

5.7 More information

Additional information, such as any health warnings or instructions for use, about infant formula or dietary foods for special medical purposes that may be considered necessary can be added in the additional information field.

6 Attachments

Model of the label

The notification must be accompanied by a model of the food label, which must show both mandatory and voluntary marking and, where possible, images designed for the packaging. The label must be clear and legible. If the model of the label provided with the notification is unclear or difficult to read or the file cannot be opened, the Finnish Food Authority will request the notifier to submit a new model of the label.

Power of attorney

If the signatory/signatories of the notification do not have the right to write the business name, a power of attorney must also be attached.

Other attachments

Other attachments that may accompany the notification include, for example, a product brochure.

7 Contact information

Questions, reports of malfunctions or problems, and comments about the Finnish Food Authority's electronic service may be emailed to elintarvikeilmoitukset@ruokavirasto.fi.

8 Entry into force

These guidelines are valid from the 14th April 2020 onwards.